responding to questions about off-label uses of Cephalon's products. Mark Macrides, a Cephalon sales representative who attended the event, confided to another Cephalon sales manager, Mike Weatherholt, his concern that Tocco's behavior was obviously and completely out of bounds. Weatherholt agreed and raised the concern up the chain of command. In response, Roy Craig called Weatherholt and berated him for being the kind of manager that a sales representative felt comfortable calling to complain about off-labeling marketing practices of other employees.

50. In 2004 alone, Cephalon planned 430 such medical education dinners for psychiatrists, with an expected attendance of 10-12 doctors per session. In prior years, sales representatives' annual budget for these and other off-label promotional activities has been $20,000-$25,000 each.

51. As physicians became more reluctant to devote time to such presentations -- because of their growing sense that they were mere marketing ploys --, Cephalon's sales representatives, with the knowledge and implied or explicit consent of their managers, began using financial inducements to convince physicians to attend the presentations. Such inducements included $500 "preceptorship" payments made by sales representatives to physicians for the putative "educational" purpose of permitting the sales representatives to observe the physician's practice for a 2-4 hour period so that the sales representative could better understand how the physician evaluates, diagnoses, and treats patients. Such "shadowing," however, in reality was intended to buy access to physicians, and to reward high-prescribers with financial inducements. Indeed, if physicians were reluctant to have a sales representative present present when they were treating patients, sales representatives paid the $500 inducement none-

theless and simply spent the time allotted to the preceptorship in the physician's waiting room or coffee room. (This was an idea proposed by sales representative Rob Rondeau at a Great Lakes Region sales meeting in 2002 or 2003 and approved by Joe Haygood, relator's former manager.) The real purpose of such preceptorship payments was not educational at all, but was to induce physicians to attend a marketing presentation in which one physician hired by Cephalon would discuss off-label use of Cephalon drugs with other physicians Cephalon paid or otherwise convinced to attend.

52. Sales representatives who balked at participating in the off-label marketing of Provigil and other Cephalon drugs through such bogus "Medical Education Programs" were rebuked and financially punished by the company. For example, Joe Haygood denied relator the bonus he had had otherwise earned through his direct sales efforts in 2002 because relator recognized such Medical Education Programs as improper off-label marketing and thus refused to utilize that marketing device as a means of keeping pace with other sales representatives who were willing to do as the company expected.

53. Cephalon further used the off-label marketing information it included in Steven Stahl's presentation to educate its own sales representatives about off-label uses of its products so that they could effectively promote the drugs off-label to physicians they "detailed." After Steven Stahl presented off-label material at Cephalon's national sales meeting in February, 2003, he noted to Mike Thiem, Cephalon's Director of Medical Liaisons, the almost exclusive focus of sales representatives in questions that followed the presentation on the off-label aspects of the presentation. When Thiem thereafter related Stahl's expressed concern about that focus to Roy Craig in relator's presence, Craig's response was that Cephalon hired Stahl and that Cephalon

tells Stahl where to draw lines regarding off-label marketing, not the other way around.

54. Cephalon's efforts to transform "educational" and "research" resources into off-label marketing tools extended generally to its use of medical liaisons. Done properly, medical liaisons between a company and the medical community are typically Ph.D.'s who are qualified to coordinate genuine research efforts among academic doctors. Roy Craig staffed Cephalon's group of medical liaisons instead with former sales representatives, and used the position primarily as an extension of Cephalon's regional marketing efforts.

55. Consistent with their marketing orientation, Cephalon's medical liaisons frequently sponsored reports on the efficacy of Cephalon products based not on double-blind control studies but on retrospective case reviews by physicians who had tried Cephalon's products off-label on their own patients and believed them to have some therapeutic effect. These case review "studies," were then provided to Cephalon's sales representatives so that they could invite other physicians to request the data from Cephalon's "medical liaisons" to support the sales representatives' suggested off-label uses of the drugs.

56. In further violation of the FDAMA, Cephalon also encouraged and directed its sales representatives to invite and encourage physicians upon whom they called to request information about off-label usage of Provigil and the other Cephalon prescription drugs from Cephalon as a means of marketing such off-label uses. Sales representatives were provided Medical Information Request Forms ("MIRFs") by Cephalon to offer to physicians in order to make such requests easier for physicians to submit. For a time, Cephalon imposed a quota on its sales representatives that required them to obtain completed MIRFs from physicians upon whom they called at a rate that exceeded one such request per day. Although that quota was discontinued,

sales representatives continued to encourage doctors to make such requests and led discussion about the availability of such information from Cephalon so that requests, when made, almost always were directed to available information that Cephalon believed would make off-label use of its products appear more attractive. Physicians were never told about the existence of information that would make off-label use of a Cephalon product less attractive. Requests to Cephalon's home office for such information from physicians were significantly less frequent than requests for favorable information.

57. For example, because available literature regarding Actiq is laden with disclaimers regarding off-label use, Cephalon's management considered it more likely to discourage than to encourage off-label use. Cephalon sales representatives thus were advised not to initiate discussions with physicians about the existence or availability of such materials and certainly never invite them to request such information. As a result, such information was rarely requested from Cephalon by physicians, whereas information that Cephalon regarded as favorable for off-label usage frequently was requested by physicians upon whom Cephalon sales representatives had recently visited.

58. Another tool that Cephalon provided its sales representatives to advance off-label sales were printouts of ICD-9-CM Diagnostic Codes related to potential off-label uses of its products. Such tools do not provide any material value to legitimate marketing efforts. Rather, they were distributed by Cephalon to sales representatives primarily so that sales representatives would coach physicians on which diagnosis codes could be used to circumvent reimbursement edits of public and private insurers that are designed to limit payment for off-label use of drugs like Cephalon's to a limited set of disease states.

59. Relator heard this coaching practice described at district sales meetings in Cancun in February 2002, in Detroit in the fall of 2002, and in Cleveland in the fall of 2003. For example, with respect to the off-label use of Provigil, sales representatives were informed at those sales meetings that physicians could be coached to use the ICD-9-CM diagnostic code for Idiopathic Hypersomnia (code 780.54, which relates to a disorder of actual sleep) to gain reimbursement for treatment of mere malaise or fatigue, which is properly identified by ICD-9-CM diagnostic code 780.7.

60. At the same time Cephalon was pressuring its existing sales force to market off-label so that the company could meet its sales growth goals, it also developed hiring criteria for potential new sales representatives that inquired whether the candidate would be able to "work within the gray area" of off-label marketing. Cephalon looked to hire only sales representatives that demonstrated understanding that off-label marketing, while explicitly disavowed in official statements of company policy and practice, was encouraged, expected, and necessary in the field in order for the company and the sales representative, individually, to reach the growth goals upon which Cephalon measured "success." It also looked to hire sales representatives who it believed could engage in extensive off-label marketing effectively -- but not too obviously.

61. In July 2006, Cephalon embarked on a co-promotion agreement with Takeda, to market Provigil in the United States. During the entire term of the agreement–which lasted until Takeda withdrew on November 1, 2008–Takeda participated in substantially the same off-label marketing schemes with respect to Provigil as Cephalon had itself engaged, as alleged above, until September 2007.

62. Cephalon's message to its sales representatives to engage in subtle but extensive off-

off-label marketing was broadly understood and implemented. Predominantly because of off-off-label marketing efforts (including the conduct set forth above), sales of Provigil rose from $25.3 million in 1999 to projected sales of $375 - $425 million for 2004. During the same period, off-label uses of Provigil had grown to account for at least 80-90% of all such sales.

63. Top bonuses earned by sales representatives most willing to market off-label similarly increased by approximately 100% over the top bonuses paid before expanding off-label sales became the subject of substantial financial incentives.

64. As of 2004, approximately 8.5% of all Provigil sales were paid for by Medicaid.

B. Cephalon Illegally Promoted Gabitril in the Same Manner as Provigil.

65. Beginning shortly after Cephalon purchased the rights to Gabitril from Abbott Laboratories in late 2000, and continuing at least until Relator's original case against Cephalon settled in principal in late 2007, Cephalon illegally promoted that drug predominantly for off-off-label indications in an essentially identical manner as it used for Provigil.

66. Gabitril is a selective gamma-aminubutyric acid ("GABA") reuptake inhibitor that has been approved by the FDA only for use as adjunctive therapy in the treatment of partial seizures in epileptic patients. Cephalon however made virtually no direct marketing effort to sell Gabitril for its FDA-approved use. Rather, Cephalon mounted a national marketing campaign to promote promote Gabitril almost exclusively for unapproved uses ranging from treatment for anxiety to insomnia to neuropathic pain relief. Indeed, because Gabitril marketability for its on-label use was so limited, Cephalon sales representatives were actually discouraged by their management from devoting marketing time to neurologists and other physicians with specialties relating to epilepsy. They were encouraged, instead, to concentrate their sales calls on psychiatrists who

were known by Cephalon to prescribe substantial amounts of anti-anxiety medications and as a cheaper alternative for some of the same off-label uses for which Pfizer's Warner-Lambert division was fined for improperly marketing Neurontin.

67. All of the violations of the law described in paragraphs 41-64, above with respect to Provigil, occurred as well with respect to Gabitril, which was generally marketed to the same physicians at the same time as Provigil.

68. Cephalon's improper marketing of Gabitril was very profitable. In just four years, Gabitril's annual sales revenues exploded from $4.4 million in the year Cephalon acquired the rights to the drug (2000) to anticipated sales of $80 - $90 million for 2004. Approximately 90% of sales for Gabitril were for off-label uses. As of 2004, more than 23% of all Gabitril sales were paid for by Medicaid.

C. Cephalon Illegally Promoted Actiq.

69. From October, 2000, when Cephalon purchased Anesta Corporation, the owner of rights to Actiq, until it settled Relator's original case in principal in late 2007, Cephalon aggressively promoted Actiq for off-label use in much the same manner as it did Provigil and Gabitril,.

70. Actiq uses Cephalon's proprietary oral transmucosal delivery system (a lollipop) to deliver fentanyl citrate, a powerful, Schedule II opioid analgesic (painkiller) to treat pain. Its sole sole FDA-approved use is for treating breakthrough cancer pain in opioid tolerant patients. "Breakthrough" cancer pain is a flare of moderate to severe pain that "breaks through" medication cancer patients use to control their persistent pain. Actiq's side effects are typical of opioids, opioids, and can range from somnolence, nausea, vomiting and dizziness to respiratory

depression, which can be life threatening.

71. From October, 2000, until the beginning of 2004, Cephalon marketed Actiq through a group of 60 to 90 Cephalon field sales representatives and managers who specialized in that product and who made sales calls primarily to pain specialists and oncologists. As a result of efforts by those sales representatives to expand the market to off-label pain applications in pain management, sales of Actiq increased from $15.2 million in 2000 to $237.5 million in 2003.

72. Specifically with a view toward expanding the market to off-label pain applications even further, in the beginning of 2004, Cephalon combined and expanded its sales forces so that all of its sales representatives and managers marketed Actiq to a broader group of physicians that included internists, general practitioners, and family practitioners who might prescribe the mediation for outpatient uses. Cephalon sales representatives marketed off-label uses of Actiq to to such physicians and coached them with respect to ICD-9-CM diagnostic codes that can be used in support of reimbursement claims.

73. Although the general effectiveness of opioids like Actiq in treating various forms of pain is well known, the self-dosing nature of Actiq's delivery system together with the high risks associated with overdosing on opioids raise serious safety concerns related to off-label – and/or inadequately supervised – use of this drug. For that reason, serious concerns have been expressed even within Cephalon about the risks inherent in its marketing decision to promote off-label use of Actiq to internists, general practitioners, and family practitioners who may not have the experience with opioids necessary to fully appreciate the dangers of the drug and the need to ensure that it is not over-prescribed or prescribed without sufficient patient education.

74. Despite these concerns, and despite the lack of scientific studies or compendia dis-

cussion to support the safety and efficacy of Actiq for any of the wide variety of outpatient off-off-label pain treatments it promotes, Cephalon changed its marketing model as of 2004 so that more sales representatives with less expertise about the drug were marketing the product to a larger pool of physicians (also with less expertise in pain management and opioids) in an effort to further accelerate the growth of off-label use of the product. The marketing of Actiq for off-label off-label use ceased only temporarily after the settlement in 2008 of Relator's and other whistleblowers' original qui tam suit. Cephalon is once again marketing Actiq and its successor drug, Fentora, for off-label use through a group of sales representatives who specialize in pain care.

75. Primarily as a result of its off-label marketing efforts, Cephalon projected total sales of Actiq in 2004 to total $325 - $375 million. As of 2004, over 90% of Actiq sales were for off-off-label uses. Approximately 8.3% of all Actiq sales are paid for by Medicaid.

VI. APPLICATION OF CEPHALON'S PRIOR MISCONDUCT TO NEW DRUGS AND CONTINUED OFF-LABEL MARKETING OF PROVIGIL POST SEPTEMBER, 2007

A. Cephalon Is Illegally Promoting Fentora.

76. in August 2004, as Actiq was about to go off patent, Cephalon made a deal with Barr Laboratories, Inc. ("Barr"), agreeing to the introduction of a generic version of Actiq by Barr in approximately February, 2007. Cephalon sold its own generic version of Actiq to Barr in bulk for packaging and labeling by that company.

77. In the meantime, Cephalon continued its efforts to gain FDA approval of its planned successor drug to Actiq: Fentora. FDA approval to market Fentora for treatment of break-through pain in opioid-tolerant patients with cancer was granted in June, 2006.

78. Fentora (fentanyl buccal effervescent tablet, delivered with Cephalon's new "Ora-Vescent® technology) is not a precise chemical or delivery-form equivalent of Actiq (transmucosal fentanyl citrate lollipop) and thus has its own, new patent protection. Consequently, it does does not face competition from true generic equivalents and can be sold at the higher prices demanded for brand name drugs without a generic.

79. Thus, in order to limit the economic consequences to Cephalon of impending competition to Actiq from its own and other generic equivalents, beginning in approximately October, 2006, Cephalon's sales force for pain medications shifted its marketing emphasis for break-through opioid painkillers from Actiq to Fentora. Cephalon's primary marketing goal during this period was to switch as many Actiq prescribing physicians as possible from Actiq to Fentora, so that such physicians and pharmacists filling their prescriptions would be less likely to write and fill prescriptions for generic equivalents of Actiq when they became available and would instead prescribe Fentora, which has no generic equivalent against which to compete, and would be far more profitable to Cephalon than Actiq once the generic hit the market.

80. Boise has been informed by reliable sources with high-placed connections within Cephalon and therefore believes that, between the time it obtained FDA approval in June, 2006 to market Fentora and the date of its September, 2007 preliminary settlement agreement with the United States regarding False Claims Act claims relating to Actiq, Provigil and Gabitril, Cephalon aggressively promoted Fentora, a fentanyl buccal tablet similar to Actiq, for off-label use in much the same manner as it has marketed Provigil, Gabitril, and Actiq.

81. Between the time it reached a preliminary settlement in Relator's and other whistle-blowers' original cases against it in September, 2007 and late 2008, Cephalon refrained from